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Ms. Evangeline Tsibris Cummings  
Environmental Protection Agency  
Office of Environmental Information  
Mail Code 2842T  
1200 Pennsylvania Avenue NW,  
Washington, DC 20460

**Re: Docket ID No. OEI-10014 - Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency**

Dear Ms.Cummings:

On behalf of the 600,000 small-business owners represented by the National Federation of Independent Business (NFIB), I am writing to offer comments on the Environmental Protection Agency's Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Disseminated Information.

NFIB is concerned that EPA's efforts to develop data quality guidelines will not adequately ensure the quality of information used or disseminated by the agency as intended by the Office of Management and Budget's (OMB's) Guidelines on Information Quality (implementing guidelines) released in January 2001. Understanding the disparate impact that regulations and their associated costs have on small businesses, as opposed to large (costs approaching \$7,000 per employee for firms with 20 employees or fewer, according to a recent study by the Small Business Administration), the quality, objectivity, utility, and especially the integrity of information disseminated by the EPA is of utmost importance, and the cornerstone of good policy development.

Ensuring the quality of data used during the regulatory development process will reduce the likelihood of EPA promulgating regulations that are not based on sound science. Regulations that are not based on sound analysis of high quality data often impose an unnecessary burden on facilities, especially smaller companies with limited resources, without providing a real environmental benefit.

Even in those instances where government agencies simply act as the distributor of data, leaving the public to draw inferences and take action on the basis of that information,

ensuring quality is still an important goal. Information disseminated by government agencies takes on a certain imprimatur. It carries with it a *de facto* agency seal of approval, whether the agency intends such a certification or not.

Given this, there is a tremendous responsibility on the part of government agencies, in their roles as public servants, to make every effort to either warrant that the information they disseminate or act upon is of the highest quality, or to disclose fully the limitations of any suspect data. It was with this in mind, that the Office of Management and Budget initially directed federal agencies to develop guidelines for assuring that the data and information they act on and disseminate meet some criterion of quality. It is indeed important that agencies examine and improve their data quality control procedures.

The Environmental Protection Agency asserts that it already has in place significant procedural mechanisms to guarantee the quality of the data it uses and disseminates. Repeatedly, EPA's guidelines refer the reader to existing guidelines that the agency has relied upon for years, suggesting that they meet or exceed any quality control concern suggested by OMB's directive. However, even accepting EPA's assertion that its policies are sufficient to ensure high quality data, its insistence on exempting numerous types of information from such rigorous procedures raises significant concerns and raises the question of whether or not EPA's guidelines truly fulfill the intention of OMB's directive.

NFIB appreciates the opportunity to offer comments on this subject, and our specific concerns are outlined below.

## **I. Implementation of EPA's Data Quality Guidelines**

EPA's draft guidelines have been proposed to comply with OMB's implementing data quality guidelines<sup>1</sup> that require federal agencies to develop and implement their own procedures for meeting OMB's data quality standards. In its implementing guidelines, OMB states, "*Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance and dissemination.*"<sup>2</sup>

While EPA's draft guidelines provide a general overview of the agency's plan to ensure the quality of information it disseminates, the draft guidelines lack sufficient details to ensure effective implementation of that required by OMB. NFIB stresses the need for EPA's guidelines to provide detailed procedures for reviewing and substantiating the quality of information before it is distributed or used. In addition, agency guidelines should establish more detailed procedures for public challenge to information believed to be not in compliance with those guidelines.

In the implementing guidelines, OMB states that federal agencies must "*ensure that their administrative mechanisms satisfy the standards and procedural requirements in the new*

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<sup>1</sup> 67 Federal Register 8451

<sup>2</sup> 67 Federal Register 8459

*agency guidelines.*”<sup>3</sup> EPA’s draft guidelines state that the agency intends to use existing policies and procedures to ensure the quality, objectivity, utility and transparency of information disseminated by the agency. Exactly how EPA policies and procedures will be incorporated into the draft guidelines remains uncertain. EPA should outline in greater detail the current programs and policies the agency intends to integrate into its guidelines and explain how the specific policies will be used to address the requirements outlined in OMB’s implementing guidelines.

## **II. Data Quality Assurances**

OMB’s implementing guidelines on data quality are intended to ensure and maximize the quality, objectivity, utility and integrity of information disseminated by federal agencies. Ensuring the usefulness of the information to the user, presenting it in an accurate and unbiased manner and protecting the information from unauthorized access or revision are criteria established as the foundation of OMB’s implementing guidance. OMB states, *“that a reproducibility standard is practical and appropriate for information that is considered influential.”*<sup>4</sup> EPA must ensure the reproducibility standard and peer review mechanism within the guidelines are strong and abided by throughout the agency.

### **Transparency and Reproducibility of Data Must Be Ensured**

In its implementing guidelines OMB states, *“the purpose of the reproducibility standard is to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed.”*<sup>5</sup> OMB’s implementing guidelines further state, *“Agency guidelines shall require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public.”*<sup>6</sup> Failure to ensure the reproducibility of data and analytic results inhibits the public’s ability to thoroughly review proposed regulations and ensure the quality of information being used by the agency.

NFIB commends EPA’s intent to make available the sources of the data used, assumptions employed, analytic methods applied and statistical procedures as stated in the draft guidelines. This is an important step towards ensuring the reproducibility of EPA’s data analysis and conclusions reached when developing regulations.

Stakeholders continue to have difficulty with the reproducibility of agency data. For example, EPA used extensive data modeling and statistical methodologies during the development of its

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<sup>3</sup> 67 Federal Register 8453

<sup>4</sup> 67 Federal Register 8455

<sup>5</sup> 67 Federal Register 8456

<sup>6</sup> 67 Federal Register 8456

recently proposed Metal Products and Machinery (MP&M) effluent limitation guidelines.<sup>7</sup> In attempting to conduct an adequate and thorough review of the proposed rule, interested parties were repeatedly frustrated by the unavailability of key supporting data.

When the proposed rule was first published only original data and results from EPA's modeling were available in the public docket. Since no detailed explanation of the agency's analytic models were available to the public, affected entities were unable to reproduce EPA's analysis or conclusions based on the information available. EPA finally made portions of its data modeling available after repeated requests by affected individuals.

EPA's thorough implementation of the reproducibility standard as outlined in its draft guidelines would ensure that problems like this would not occur in the future. By ensuring the reproducibility of data, EPA would promote thorough public review of proposed regulations allowing final rules to be based on sound analysis.

### **EPA Should Strengthen the Guideline's Peer Review Mechanism**

In its implementing guidance, OMB states, "*If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity.*"<sup>8</sup> EPA's intent to use the agency's existing "Peer Review Policy" to satisfy the peer review component of OMB's implementing guidelines is not sufficient. Existing procedures are inadequate because not all agency information used or disseminated by the agency is currently peer reviewed.

For example, a recent EPA rule where peer review was necessary but not used was the agency's rule heightening the reporting standard for lead under the Toxics Release Inventory (TRI). EPA used persistent, bio-accumulative and toxic (PBT) criteria to justify lowering the reporting threshold for lead from 25,000 pounds to 100 pounds. EPA did not subject the use of PBT criteria, which was developed to evaluate synthetic organic chemicals, for evaluating metals to an external, independent peer review before using it to develop the lowered reporting thresholds for lead. The agency did, however, recognize the need for peer review by the Science Advisory Board (SAB) stating, "...EPA believes that it would be appropriate to seek external scientific peer review from its Science Advisory Board, and EPA intends to do so,"<sup>9</sup> but only after the rule was finalized.

NFIB is seriously concerned that EPA's policy for peer review gives the agency too much discretion as to what information is peer reviewed and recommends EPA establish a standardized process for peer review. Applying a stringent peer review mechanism for information used by the agency will result in rules that are acceptable to OMB. EPA must follow OMB's implementing guidelines and subject information used for agency decisions to peer review by an independent, external panel to ensure its quality and objectivity.

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<sup>7</sup> 76 *Federal Register* 423

<sup>8</sup> 67 *Federal Register* 8459

<sup>9</sup> 66 *Federal Register* 4518

However, OMB guidelines state that if an affected person can make a persuasive argument that the result of an independent review is faulty, that outcome can be invalidated. EPA failed to address this issue in their draft guidelines. NFIB urges EPA to include in their data quality guidelines a mechanism that ensures an affected individual can rebut peer-reviewed information.

### **III. Exemptions From Data Quality Guidelines**

OMB's implementing guidelines were intended to raise the level of objectivity, utility and integrity of all information disseminated by federal agencies. NFIB is seriously concerned EPA is attempting to exclude vast amounts of information from being subjected to the guidelines. EPA's limited applicability of the guidelines would undermine the very intent of OMB's implementing data quality guidelines by not subjecting all information disseminated and used by the agency to higher quality standards.

The EPA guidelines provide no rigorous standard for determining when the data quality criteria can be ignored. ***This effectively makes the guidelines worthless as a tool for improving agency behavior.*** Presumably, before OMB's directive, EPA was not in the habit of seeking out bad quality data for use and dissemination, and there is no reason to believe it will do this in the future. The importance of developing data quality guidelines is to commit agencies to some standard for ensuring a process leading to optimal data quality. If EPA stipulates that its guidelines essentially apply at its discretion, no such process is achieved.

EPA should commit to warranting that every time it disseminates information, the information meets the standards laid out in its guidelines. This should be done explicitly in the form of some kind of written notice accompanying the information. If, for some reason, EPA has decided that the costs of applying the guidelines to specific information are prohibitive, this too should be explicitly disclaimed. The disclaimer should include EPA's analysis justifying its rejection of the guidelines for the given information. By explicitly warranting or disclaiming that the information has been subjected to the quality standards, EPA would be committing itself to a principled procedure upon which the public could rely. Explicit notices of this type will inform the public and allow for important criticism in situations where the agency might have abused its discretion.

### **Public Filings Exemption**

While NFIB understands certain information gathered by EPA through public filings may warrant exemption, wholesale exclusion of all public filings from the guidelines is inappropriate. EPA's exemption of public filings required by statutes and regulations, such as the Toxic Release Inventory, from compliance with the data quality guidelines is unacceptable. Failing to subject this information to the quality standards established in the guidelines will have an adverse effect on the quality of information the agency is required by law to disseminate to the public.

EPA avoids the intended goal of OMB's implementing guidelines by suggesting that required public filings, such as TRI, are not "disseminated" by the agency. EPA states in the draft

guidelines that the agency considers information disseminated “...if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it...”<sup>10</sup> When the public accesses TRI data on the EPA website or through agency publications, the public may reasonably believe that EPA endorses the information it has released and posted on their website or published in agency reports.

EPA disseminates environmental data gathered under the TRI, and other public filings, to the public through the agency’s information management systems. EPA specifically states in their draft guidelines that “providing and facilitating access to information about local environmental issues and conditions...”<sup>11</sup> gives the public the ability to use the information in their communities. EPA’s draft guidelines further state that city planners, homeowners, teachers, engineers and community activists use information provided by the agency.<sup>12</sup> By not subjecting this information to the guidelines, EPA is doing a disservice to the public by providing inaccurate information that will be used on the job, in schools or in communities. Faulty information can result in the public misallocating valuable resources to deal with imaginary environmental problems, while overlooking real environmental dangers. If information is disseminated to the public for use, as the agency infers, then that data must comply with the data quality guidelines.

#### *Exemption of Information Used During Rulemaking*

Information used during the rulemaking process, both completed and ongoing, makes up much of the information used by federal agencies. EPA has indicated the agency’s data quality guidelines will not apply to information in proposed rulemakings, and that alleged errors would be handled only through the rule’s notice and comment process. It is imperative that information used during the rulemaking process complies with the data quality standards established in the guidelines to ensure that all information used in developing regulations is of high quality.

OMB’s implementing guidelines state that agencies shall facilitate public review by establishing an administrative mechanism for affected individuals to seek and obtain timely correction of information that does not comply with the data quality standards.<sup>13</sup> Relying on the rulemaking process for correction of bad information is not timely as required by OMB since changing incorrect data during the rulemaking process can be an onerous and often time-consuming process. The rulemaking process can take several years to reach completion. Furthermore, the actual time afforded to affected individuals to identify and file for correction of bad information during this process is limited to public comment periods, some as short as 30 days.

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<sup>10</sup> Environmental Protection Agency, “Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.” Section 1.2 (Page 14).

<sup>11</sup> Environmental Protection Agency, “Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.” Background and Discussion, Section 2.3 (Page 2).

<sup>12</sup> Environmental Protection Agency, “Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.” Background and Discussion, Section 2.4 (Page 3).

<sup>13</sup> 67 *Federal Register* 8459

NFIB is further concerned that by excluding data used during a rulemaking, affected individuals may not have an opportunity to comment appropriately if faulty data was embedded in the models used to develop the proposed rule. If the data used in EPA models was faulty then the analytic results used during the rulemaking would also be flawed. The public would only have an opportunity to comment on the flawed modeling results presented by the agency, instead of models that represent reality.

Information and models used to develop rules must be subjected to the data quality guidelines regardless of whether or not that information is used in a rulemaking to ensure correct information is used in all EPA actions. This will further ensure the public an opportunity to perform a thorough review of the data and analytic results used to develop the proposed rule. NFIB urges EPA to apply all information used during the rulemaking process to the data quality guidelines, including subjecting information to the data quality petition process if affected individuals identify incorrect information.

#### **IV. Data Quality Petition Process**

OMB's implementing guidelines state that a correction process ensuring a timely, streamlined process to recognize and correct identified errors must be provided for affected individuals. NFIB is concerned EPA's current process does not meet the level of assurance detailed in OMB's implementing guidelines. EPA's draft guidelines do not provide sufficient details of how the agency will implement the petition process, establishes no timeframe for complaint resolution, and provides no mechanism for public notification. EPA must establish a firm set of procedures for contesting information to ensure successful correction of bad information as intended by OMB's guidelines.

#### **EPA Should Include a Timeframe for Complaint Resolution**

OMB's implementing guidelines state, "*Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.*"<sup>14</sup> EPA currently offers no timeframe for the agency's complaint resolution mechanism. Establishing a specific timeframe for the complaint process is essential to ensure timely correction of inaccurate information. Without establishing a timeframe the process is too open-ended and the agency has the ability to avoid complaints altogether. NFIB urges EPA to develop a reasonable timeframe for processing complaints to ensure a timely and informative response to all petitioners and that appropriate corrections are made.

OMB's implementing guidelines do not indicate the establishment of any time limit for affected individuals to identify and seek correction of faulty information. EPA's draft guidelines did not directly suggest any deadlines for petitions. However, EPA did infer that the agency may not consider data quality petitions made during a rulemaking that are submitted after the comment period. Since the intent of the petition process is to ensure bad information is corrected, NFIB further recommends that no deadline be established for an affected individual to file a complaint.

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<sup>14</sup> Id.

### **Public Should Be Notified of Complaint**

The public should know if a complaint has been filed alleging certain information to be flawed. Public notification would ensure that individuals using the information would not rely on data that may be inaccurate and allows them to scrutinize the information more carefully to ensure its validity. EPA does not identify in their draft guidelines any mechanism to notify the public that a complaint was filed on certain information. NFIB urges EPA to provide public notice when a complaint is filed with the agency citing that certain information could be incorrect. Furthermore, complaint notification should be disseminated to the public in the same fashion the original information was disseminated by EPA to ensure that those who obtained the information originally receive notice of its alleged inaccuracy.

### **Retroactive Application for Information Used After October 1, 2002**

OMB's implementing guidelines are intended to apply to information disseminated or used on or after implementation of the data quality guidelines (October 1, 2002) regardless of when the information was first disseminated. EPA's draft guidelines followed OMB's implementing guidelines but failed to provide additional details of how the agency would ensure the quality of data that is produced before October 1, 2002 but disseminated or used again after implementation of the guidelines. Every day that a specific piece of information is used by the agency, that it continues to be posted on the website where it can be used or it continues to be made available to the public, that piece of information should be considered a new dissemination and therefore applicable to the data quality guidelines. NFIB urges EPA to ensure affected individuals the right to contest information used or disseminated by the agency on or after October 1, 2002, regardless of when that information was first made available to the public or used by the agency.

### **Administrative Appeals Process**

OMB states in their implementing guidelines that, *"if the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency."*<sup>15</sup> OMB further explained that to provide an objective process the agency must *"ensure that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement."*<sup>16</sup>

EPA's draft guidelines do not provide sufficient information to understand how the agency plans to implement an appeals process. The draft guidelines state that the Assistant Administrator within the appropriate program office or region, along with the Office of Environmental Information (OEI), would be responsible for establishing an executive panel to review the appeal, but no details are offered on the makeup of this panel. Furthermore, the draft guidelines state the panel may only offer a recommendation, leaving the final decision to the Assistant

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<sup>15</sup> Id.

<sup>16</sup> Id. at 8458



Administrator. This mechanism leaves too much discretion to the program office that has a vested interest in the outcome of the appeals process. NFIB urges EPA to establish an independent administrative appeal process to review the agency's initial decision to ensure an objective process as required by OMB.

### **Definition of "Affected Person"**

NFIB applauds EPA's definition of an "*affected person*" as someone who "*may benefit or be harmed by the disseminated information,*"<sup>17</sup> including persons who use information, as stated in EPA's draft guidelines. The utility of information disseminated from agencies is an integral part of OMB's data quality standards. Therefore, EPA took the right position by including in its definition of an "affected person," any individuals whose efforts are hindered or compromised by faulty data.

### **V. Risk Assessment**

OMB's implementing guidelines state that, "*With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act (SDWA) Amendments of 1996 (42 USC § 300g-1(b)(3)(b)).*"<sup>18</sup> The SDWA provisions call for the use of "*best available, peer-reviewed science*"<sup>19</sup> and "*data collected by accepted methods or best available methods.*"<sup>20</sup> EPA indicated in their draft guidelines the agency's intention to adapt the SDWA principles with some changes but did not provide details of how the agency plans to incorporate the SDWA standards into their data quality guidelines. EPA must make available additional information on how the agency plans to adapt and implement the SDWA principles prior to finalization of the data quality guidelines to ensure sufficient time for public comment.

### **VI. Conclusion**

EPA's efforts to develop data quality guidelines do not go far enough to ensure the quality of information used or disseminated by the agency as intended by OMB's implementing guidelines. The draft guidelines provided by EPA seem to offer only an outline of the agency's intended guidelines and fail to provide detailed information as to how they will execute the program and ensure adherence throughout the agency. EPA must establish strong data quality guidelines that are easy to understand and that provide specific details of how the guidelines will be implemented within the agency to maximize the quality of information.

To ensure a higher standard for data quality as intended by OMB, all information disseminated and used by the agency must be subjected to the data quality guidelines. The agency's attempt to

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<sup>17</sup> Environmental Protection Agency, "Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," Line 715, Page 22.

<sup>18</sup> 67 *Federal Register* 8460

<sup>19</sup> *Id.* at 8457

<sup>20</sup> *Id.*

exempt vast amounts of information, such as public filings and information used during rulemakings, would seriously undermine any attempt to strengthen data quality within the agency.

Ensuring and maximizing the quality of data used during the regulatory development process would reduce the likelihood of EPA promulgating unnecessary regulations and creating an unnecessary burden on regulated entities. To produce the greatest environmental benefit, EPA would be best served to develop a strong data quality program.

NFIB appreciates the opportunity to provide comments on EPA's Draft Data Quality Guidelines, and we look forward to working with EPA to implement changes in the regulatory scheme that are beneficial to the nation's economic and environmental health. If you have any questions, or require and additional information, please do not hesitate to contact me.

Sincerely,

Andrew M. Langer  
Manager, Regulatory Policy

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